

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended) An assembly for crossing occlusive or stenotic material, the assembly comprising:

a guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire; and

a drive shaft rotatably and translatable extending through the axial passage of the guidewire;

wherein the drive shaft comprises a distal tip that can be rotated and advanced to create a path through the occlusive or stenotic material.
- 2.-3. (Canceled)
4. (Original) The assembly of claim 3 further comprising a detachable motor coupled to a proximal end of the drive shaft that can impart a rotational movement to the distal tip of the drive shaft.
5. (Original) The assembly of claim 1 wherein a proximal end of the drive shaft can be manually rotated.
6. (Original) The assembly of claim 1 wherein the distal tip is flattened and twisted.
7. (Original) The assembly of claim 1 wherein the distal tip has a width that is larger than the width of the drive shaft.
8. (Original) The assembly of claim 1 wherein a distal end of the hollow guidewire is steerable.

9. (Original) The assembly of claim 1 further comprising a housing coupled to the proximal end of the hollow guidewire.

10. (Original) The assembly of claim 9 wherein the housing comprises an actuator, wherein the drive shaft defines a longitudinal axis, and wherein movement of the actuator moves the drive shaft along the longitudinal axis.

11. (Original) The assembly of claim 10 wherein the actuator can extend the drive shaft up to 5 centimeters beyond the distal end of the hollow guidewire.

12. (Original) The assembly of claim 9 wherein the housing comprises an infusion or aspiration port coupled to the hollow guidewire.

13. (Original) The assembly of claim 1 wherein the hollow guidewire is maintained in a substantially stationary position while the drive shaft is rotated and advanced.

14. (Original) The assembly of claim 1 wherein the distal tip of the drive shaft is radio-opaque.

15. (Original) The assembly of claim 1 wherein the drive shaft has riflings which facilitate proximal transportation of a removed occlusive or stenotic material.

16. (Original) The assembly of claim 1 further comprising a support system having a distal end, wherein the hollow guidewire passes through the support system such that the distal tip is positioned beyond the distal end of the hollow guidewire and support system.

17. (Original) The assembly of claim 16 wherein the support system comprises placing means disposed near the distal end for centering or directing the distal end of the support system within the body lumen.

18. (Original) The assembly of claim 16 wherein the hollow guidewire is advanceable through a vasculature without the use of the support system.

19. (Original) The assembly of claim 1 wherein the drive shaft defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

20. (Currently amended) A guidewire system for passing through an occlusion or stenosis, the system comprising:

a hollow guidewire having a steerable distal end, a proximal end, and a lumen therebetween, wherein the hollow guidewire has an outer diameter between approximately 0.009 inches and 0.035 inches and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire;

a drive shaft movably disposed within the hollow guidewire, the drive shaft having a longitudinal axis, a proximal end, and a distal tip portion;

a rotating mechanism coupled to the proximal end of the drive shaft; and

an actuator coupled to the drive shaft for controlling the axial movement of the drive shaft;

wherein the activation of the actuator advances the rotatable drive shaft from a retracted position to an extended position, wherein the rotating distal tip portion in an extended position can create a path through the occlusion or stenosis.

21. (Original) The system of claim 20 wherein the distal tip portion is flattened and twisted.

22. (Original) The system of claim 20 wherein the distal tip portion creates a path forward of the hollow guidewire that is at least as large as the outer radius of the hollow guidewire.

23. (Original) The system of claim 20 wherein the distal tip portion creates a path forward of the hollow guidewire that is no larger than the outer radius of the hollow guidewire.

24. (Original) The system of claim 20 wherein the distal tip portion comprises a plurality of wires connected at their ends, a plurality of wires unconnected at their ends, spiral with a blunt tip, or a loop.

25. (Canceled)

c - 26. (Withdrawn) The system of claim 20 wherein the distal tip portion is deflectable, sharpened, embedded, roughened, or coiled.

27. (Original) The system of claim 20 wherein the rotating mechanism and actuator are coupled together such that the drive shaft is rotated and advanced simultaneously.

28. (Original) The system of claim 20 wherein the rotating mechanism and actuator are independently rotated and advanced.

29. (Original) The system of claim 20 wherein the rotating mechanism is removably attached to the drive shaft.

30. (Original) The system of claim 20 wherein the lumen of the hollow guidewire is configured to aspirate fluids and debris from or infuse fluids into the occlusion or stenosis.

31. (Currently amended) A system for crossing an occlusion or stenosis within a body lumen, the system comprising:

an elongate member having a proximal end, a distal end, and an axial passage extending to a distal tip at the distal end, wherein the elongate member has an outer diameter between approximately 0.009 inches and 0.035 inches and a torqueability and pushability to be advanced through a body lumen without the need of a guidewire;

a drive shaft rotatably and translatable receivable in the axial passage of the elongate member; and

a flattened and twisted distal tip attached to the drive shaft that can create a path in front of the elongate member, wherein the drive shaft and distal tip are moveable between an axially retracted configuration and an axially extended configuration.

32. (Original) The system of claim 31 wherein the distal tip in the axially retracted configuration has a profile no larger than that of the distal tip

33. (Original) The system of claim 31 wherein the distal tip is sharpened.

34. (Original) The system of claim 31 wherein the distal tip comprises at least two turns.

35. (Original) The system of claim 31 wherein the elongate member is a hollow guidewire.

36. (Original) The system of claim 35 wherein the hollow guidewire has a steerable tip.

37. (Canceled)

38. (Original) The system of claim 31 further comprising a rotating mechanism coupled to a proximal end of the drive shaft to facilitate rotation of the drive shaft.

39. (Original) The system of claim 38 wherein the mechanical rotating mechanism is detachable from a proximal end of the drive shaft.

40. (Withdrawn) A system for crossing an occlusion or stenosis within a body lumen, the system comprising:

an elongate member having a proximal end, a distal end, and an axial passage;
a drive shaft comprising a longitudinal axis rotatably and translatable disposed in the axial passage of the elongate member, wherein a proximal portion of the drive shaft is removably attached to a rotating mechanism and a distal tip is deflectable off of the longitudinal axis;

wherein the rotating mechanism rotates the drive shaft so that a distal tip of the drive shaft can be advanced beyond the distal end of the elongate member to create a path that is large enough to pass the elongate member through the occlusion or stenosis.

41. (Withdrawn) The system of claim 40 wherein the elongate member has a steerable tip.

42. (Withdrawn) The system of claim 40 wherein the elongate member has an outer diameter between approximately 0.035 inches and 0.009 inches.

43. (Withdrawn) The system of claim 40 wherein the path created by the distal tip is at least as large as the diameter of the distal end of the elongate member.

44. (Withdrawn) The system of claim 40 wherein the path created by the distal tip is no larger than the diameter of the distal end of the elongate member.

45. (Withdrawn) The system of claim 40 wherein the drive shaft can extend up to 5 centimeters beyond the distal end of the elongate member.

46. (Withdrawn) The system of claim 40 wherein the drive shaft is movable between a retracted position and an extended position, wherein the distal tip in the retracted position can be completely disposed within the elongate member.

47. (Withdrawn) The system of claim 40 wherein the drive shaft is movable between a retracted position and an extended position, wherein the distal tip in the retracted position at least partially extends out of the distal end of the elongate member.

48. (Withdrawn) The system of claim 40 further comprising a support or access system disposed over the elongate member, wherein the rotating mechanism is detached from the drive shaft prior to positioning the support or access system over the elongate member.

49. (Withdrawn) The system of claim 40 wherein the axial passage of the elongate body is configured for infusion or aspiration of the body lumen.

50. (Withdrawn) A method of crossing an occlusion or stenosis within a body lumen comprising:

positioning a hollow guidewire comprising a drive shaft into the body lumen;
rotating the drive shaft within a lumen of the guidewire;
extending the drive shaft from a retracted configuration to an extended configuration; and

advancing the distal portion of the drive shaft into the occlusion or stenosis.

51. (Withdrawn) The method of claim 50 wherein the drive shaft is simultaneously extended and rotated.

52. (Withdrawn) The method of claim 50 wherein the drive shaft is independently extended and rotated.

53. (Withdrawn) The method of claim 50 wherein the drive shaft in the extended configuration creates a path at least as large as the perimeter of the distal end of the elongate member.

54. (Withdrawn) The method of claim 50 further comprising advancing the guidewire through the body lumen without the use of a separate guidewire.

55. (Withdrawn) The method of claim 50 further comprising maintaining the position of the guidewire during the advancing of the drive shaft.

56. (Withdrawn) The method of claim 50 further comprising moving a support system through the body lumen.

57. (Withdrawn) The method of claim 56 wherein the support system is moved over a guidewire, wherein the guidewire is removed from the support system prior to positioning the hollow guidewire within the support system and body lumen.

58. (Withdrawn) The method of claim 56 wherein the support system is moved through the body lumen over the hollow guidewire.

59. (Withdrawn) The method of claim 56 wherein a rotating mechanism is detached from the drive shaft prior to moving the support system over the hollow guidewire.

60. (Withdrawn) The method of claim 56 further comprising infusing or aspirating the body lumen through the support system.

61. (Withdrawn) The method of claim 56 further comprising maintaining the position of the support system in the body lumen during the extending step.

62. (Withdrawn) The method of claim 56 further comprising using the support system to perform a balloon angioplasty, stent placement, ultrasound, or an atherectomy.

63. (Withdrawn) The method of claim 50 further comprising infusing or aspirating the body lumen through the hollow guidewire.

64. (Withdrawn) The method of claim 63 wherein the infusing or aspirating is performed simultaneously with the creation of the path.

65. (Withdrawn) The method of claim 63 wherein infusing comprises delivering at least one of a therapeutic material, rinsing material, a dye, and a diagnostic material through the elongate member.

66. (Withdrawn) The method of claim 50 further comprising steering the distal end of the elongate member.

67. (Currently amended) A kit comprising:
a hollow guidewire having an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire;
a rotatable drive shaft having a shaped distal tip, the rotatable drive shaft being removably received within the passage of the hollow guidewire;
instructions for use in passing through occlusions in a body lumen comprising rotating the drive shaft within the steerable hollow guidewire and advancing the drive shaft into the occlusive material to create a path through the occlusive material; and
a package adapted to contain the hollow guidewire, rotatable drive shaft, and the instructions for use.

68. (Original) The kit of claim 67 wherein rotation of the shaped distal tip creates a profile that is at least as large as the outer diameter of the hollow guidewire.

69. (Original) The kit of claim 67 wherein rotation of the shaped distal tip creates a profile that is no larger than the outer diameter of the hollow guidewire.

70. (Cancelled)

71. (Withdrawn) The kit of claim 67 wherein the shaped tip comprises a deflected tip, a sharpened tip, a coiled tip, or a roughened tip.

72. (Original) The kit of claim 67 wherein the hollow guidewire has a steerable distal portion.

73. (Original) The kit of claim 67 further comprising a support or access system, wherein the support or access system is sized to removably receive the hollow guidewire and position a distal end of the hollow guidewire adjacent the occlusion.

74. (Original) The kit of claim 73 wherein the support or access system comprises an atherectomy catheter, support catheter, a balloon angioplasty catheter, a stenting catheter, infusion catheter, rotational catheter, extractional catheter, or a guiding catheter.

75. (Original) The kit of claim 74 further comprising a second guidewire, wherein the support or access system is advanced through the body lumen over the second guidewire.

76. (Original) The kit of claim 67 further comprising a power supply and a motor, wherein the motor can be coupled to a proximal end of the rotatable drive shaft so as to rotate the drive shaft.

77. (Original) The kit of claim 76 further comprising attachment mechanism for detachably coupling the motor to the drive shaft.

78. (Original) The kit of claim 76 wherein the power supply comprises a plastic sheath cover.

79. (Original) The kit of claim 77 wherein the motor is movably housed within a housing, wherein the housing is coupled to the hollow guidewire through a luer.

80. (Currently amended) An assembly for crossing occlusive or stenotic material, the assembly comprising:

a guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire; and

a drive shaft movably extending through the axial passage of the guidewire;

wherein the drive shaft comprises a distal tip that extends beyond the guidewire to create a path through the occlusive or stenotic material.

81. (New) An assembly for crossing occlusive or stenotic material, the assembly comprising:

a guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire; and

a drive shaft movably extending through the axial passage of the guidewire;

wherein the drive shaft comprises a distal tip that extends distally beyond the guidewire,

wherein the drive shaft may be oscillated or rotated to create a path through the occlusive or stenotic material.